IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EAGLE PHARMACEUTICALS, INC., Plaintiff, v. SLAYBACK PHARMA LLC, Defendant.	C.A. No. 18-1953-CFC **PUBLIC VERSION**

OPENING BRIEF IN SUPPORT OF SLAYBACK PHARMA LIMITED LIABILITY COMPANY'S MOTION FOR JUDGMENT ON THE PLEADINGS

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

Cases

Other Authorities

NATURE AND STAGE OF THE PROCEEDINGS

On December 11, 2018, Plaintiff Eagle Pharmaceuticals, Inc. ("Eagle" or "Plaintiff") filed its Complaint (D.I. 1) against Defendant Slayback Pharma Limited Liability Company ("Slayback"). Plaintiff's Complaint alleges that Slayback's proposed 505(b)(2) product infringes U.S. Patent Nos. 9,265,831 ("the '831 patent"); 9,572,796 ("the '796 patent"); 9,572,797 ("the '797 patent"); and 10,010,533 ("the '533 patent") (collectively, the "patents-in-suit"), which Slayback has challenged under 21 U.S.C. § 355(b)(2)(A)(iv) ("Paragraph IV"). Plaintiff does not contend that Slayback literally infringes the patents-in-suit. Rather, Plaintiff's complaint alleges that Slayback infringes the patents-in-suit under the doctrine of equivalents ("DOE"). Pursuant to Fed. R. Civ. P. 12(c), Slayback moves for judgment on the pleadings.

SUMMARY OF ARGUMENT

Plaintiff does not assert that Slayback's proposed product literally infringes the claims of the patents-in-suit. Plaintiff thus concedes that Slayback's proposed product cannot literally infringe any claim of the patents-in-suit. All of the independent claims of these patents require a pharmaceutically acceptable fluid which contains some combination of propylene glycol and polyethylene glycol. [redacted]

Additionally, Plaintiff cannot rely on the doctrine of equivalents to prove infringement of the patents-in-suit. "[W]hen a patent drafter discloses but declines to claim subject matter . . . [that] action dedicates that unclaimed subject matter to the public." *Johnson & Johnston Assocs. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (citing *Maxwell v. J. Baker, Inc.,* 83 F.3d 1098, 1106 (Fed. Cir. 1996)). [redacted]

[redacted]

STATEMENT OF FACTS

I. The Patents-In-Suit

In 2018, Eagle obtained approval to market Balrapzo® pursuant to NDA No. 205580. Since its approval, Eagle has listed six patents in the Orange Book for Balrapzo®: U.S. Patent No. 8,609,707, the '831 patent, the '796 patent, the '797 patent, U.S. Patent No. 8,791,270, and the '533 patent.[1]

The patents-in-suit share inventors and a common chain of priority. Each of the patents names Nagesh R. Palepu and Phillip Christopher Buxton as inventors, and each claims earliest priority through Provisional Application No. 61/299,100, filed January 28, 2010. The claims of the patents-in-suit are generally directed to non-aqueous liquid bendamustine containing compositions which include the solvents propylene glycol and polyethylene glycol.[2]

[1] [redacted].

[2] The claims of the patents-in-suit are reproduced in attached Exhibit A.

As set forth in more detail *infra*, the patents-in-suit each identify, but do not claim, [redacted].[3]

II. Slayback's 505(b)(2) Product

On August 31, 2018, Slayback filed an NDA under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act seeking FDA approval to market its product, [redacted]

[3] The patents-in-suit each contain a substantially identical specification. For purposes of this motion, cites to the '831 patent specification are merely intended as representative of all the patents-in-suit.

[redacted]

Slayback's NDA for its 505(b)(2) product contains Paragraph IV certifications with respect to all six Orange Book listed patents for Balrapzo®. On October 31, 2018, Slayback sent Plaintiff a Notice Letter containing its Paragraph IV certifications for each of Slayback's six Orange Book-listed patents, including the basis for its disclosure-dedication arguments regarding the patents-in-suit. [redacted] Plaintiff filed a complaint against Slayback on December 11, 2018, alleging that Slayback's 505(b)(2) product infringes the patents-in-suit (D.I. 1).

ARGUMENT

"Judgment on the pleadings should only be granted if it is clearly established that no material issue of fact remains to be resolved and that the movant is entitled to judgment as a matter of law." *Rodriguez v. Stevenson,* 243 F. Supp. 2d 58, 62 (D. Del. 2002) (Sleet, J.) (granting Rule 12(c) motion). A Rule 12(c) motion is especially useful where, as here, "only questions of law

[4] [redacted]

[5] [redacted]

remain to be decided by the district court." 5C Charles A. Wright & Arthur R. Miller, *Federal Practice & Procedure*(s) 1367 (2004) (citations omitted).

In evaluating a motion for judgment on the pleadings, a court may consider the pleadings, exhibits attached to the pleadings, matters of public record, and any documents "integral to or explicitly relied upon" in the pleadings *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997); *Pension Benefit Guar. Corp. v. White Consol., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1193). Where the factual allegations in a complaint contradict a document attached to the pleadings, however, the document controls. *See ALA, Inc. v. CCAIR, Inc.,* 29 F.3d 855, 859 n.8 (3d Cir. 1994); *Sisk v. Sussex Cnty.,* Civ. No. 11-121-RGA, 2012 U.S. Dist. LEXIS 76251, at *19-20 (D. Del. June 1, 2012). Here, Plaintiff's complaint and Slayback's Answer and Counterclaims explicitly rely on the patents-in-suit and Slayback's 505(b)(2) application. Accordingly, such documents may be considered by the Court in connection with this motion. *See In re Bendamustine Consol. Cases*, No. 13-2046, 2015 U.S. Dist. LEXIS 55963, at *8-9 (D. Del. Apr. 29, 2015) ("The court is satisfied that the . . . patents, their file histories, as well as the Moving Defendants' ANDA filings are all properly before the court, even at this preliminary stage. . . . [T]he patents and the ANDA filings comprise the entire basis for Cephalon's complaints against the Moving Defendants—Cephalon's argument that they are not 'integral' is puzzling.").

I. Slayback's Proposed Product Cannot Literally Infringe The Patents-in-Suit

Slayback's proposed product cannot literally infringe any claim of the patents-in-suit. As set forth above, all of the independent claims of the patents-in-suit require some combination of propylene glycol and polyethylene glycol. [redacted]

[redacted]

If the independent claims are not literally infringed, then it necessarily follows that the narrower claims that depend from those claims cannot be literally infringed. *See Wahpeton Canvas Co., Inc. v. Frontier Inc.,* 870 F.2d 1546, 1553 n.9 (Fed. Cir. 1989).

II. The Disclosure-Dedication Rule Bars Plaintiff's Claims For Infringement Of The Patents-in-Suit Under The Doctrine Of Equivalents

"[W]hen a patent drafter discloses but declines to claim subject matter . . . [that] action dedicates that unclaimed subject matter to the public." *Johnson & Johnson Assocs. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (citing *Maxwell v. J. Baker, Inc.*, 83 F.3d 1098, 1106 (Fed. Cir. 1996)). "[A] patentee cannot narrowly claim an invention to avoid prosecution scrutiny by the PTO, and then, after patent issuance, use the doctrine of equivalents to establish infringement because the specification discloses equivalents." *Id.* at 1055. Application of the disclosure-dedication rule is a question of law. *Pfizer, Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1378 (Fed. Cir. 2005).

To fall within the disclosure-dedication rule, the disclosure must be sufficiently specific to permit a person of ordinary skill in the art to identify the unclaimed subject matter. *Pfizer, Inc.*, 285 F.3d at 1387-79 (quoting *PSC Comput. Prods., Inc. v. Foxconn Int'l, Inc.,* 355 F.3d 1353, 1360 (Fed. Cir 2004)). Moreover, unclaimed subject matter must be identified "as an alternative to a claim limitation." *Id.* at 1378. However, no specific language is required for an embodiment to be dedicated to the public. *CSP Techs., Inc. v. Sud-Chemie AG*, 643 F. App'x 953, 958-59 (Fed. Cir. 2016) (citations omitted).

As with an analysis under the doctrine of equivalents, analysis of disclosure-dedication is conducted on an element-by-element basis. *See Johnson*, 285 F.3d at 1052; *Reckitt Benckiser Pharms., Inc. v. Dr. Reddy's Labs. S.A.*, No. 14-1451, 2017 U.S. Dist. LEXIS 140633, at *10 (D. Del. Aug. 31, 2017); *Aventis Pharms., Inc. v. Barr Labs., Inc.*, 335 F. Supp. 2d 558, 575-76 (D.N.J. 2004). Specifically, a finding of dedication does not require disclosure of a complete alternative *embodiment*, but only disclosure of an alternative to a particular claim limitation. *Johnson*, 285 F.3d at 1055.

[redacted] There, Judge Sleet granted a motion for judgment on the pleadings based on the disclosure-dedication rule. In *In re Bendamustine*

[6] All emphasis in this document is added unless otherwise noted.

Consol. Cases, the common specification included a list of more than twenty possible organic solvents, but claimed only one. Defendants used one of the disclosed but unclaimed solvents in their proposed ANDA products. Because this solvent was disclosed but not claimed, Judge Sleet found that it had been dedicated to the public:

> This is not a situation where the specification makes a "generic reference" to a broad genus, such as all "organic solvents." Rather, . . . the specification identifies *precise alternatives* to [tertiary-butyl alcohol]. Thus, it is unnecessary to inquire into whether "one of ordinary skill in the art could identify the subject matter that had been disclosed [but] not claimed" – the list is self-explanatory.

In re Bendamustine Consol. Cases, 2015 U.S. Dist. LEXIS 55963, at *11 (citations omitted; emphasis in original).

[redacted] *See Johnson & Johnson Associates,* 285 F.3d at 1055 ("Having disclosed without claiming the steel substrates, Johnston cannot now invoke the doctrine of equivalents to extend its aluminum limitation to encompass steel."); *Aventis Pharms.*, 335 F. Supp. 2d at 578 (Where "[t]he plain language of the patent specification [] makes clear that the unclaimed excipients belong to the same class of therapeutically inert ingredients as those claimed, and moreover, that they can be used in the composition . . . [the patentee has] dedicated these ingredients to the public, and cannot now reclaim these excipients through application of the doctrine of equivalents.").

CONCLUSION

For at least the foregoing reasons, Slayback respectfully requests that the Court grant its motion for judgment on the pleadings.

Dated: January 4, 2019

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CERTIFICATE OF SERVICE

I certify that on January 4, 2019, a copy of Defendant's Opening Brief in Support of Its Motion for Judgment on the Pleadings and the Exhibits thereto were caused to be served by email on the following counsel:

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